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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,206	10/26/2000	Daniel E.H. Afar	G&C 129.21-US-U1	3714

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	16

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/697,206	Applicant(s) AFAR ET AL.	
	Examin r MINH-TAM DAVIS	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,32,34 and 44-61* is/are pending in the application.

4a) Of the above claim(s) *46-49, 52-55, 58-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *29,30,32,34,44,45,50,51,56 and 57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group X, claims 30, 32, 34, species bladder cancer, in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the level of expression of a gene could be measured either by measuring mRNA levels or protein levels as the gene is transcribed and translated, and thus all claims 29, 30, 32, 34, and new claims 44-61 should be examined together without undue burden for the Examiner. This is not found persuasive because of the following reasons: 1) The two methods differ in method steps and reagents used, since the structure of mRNAs is different from that of the encoded protein and 2) Detection of overexpression levels of mRNAs does not necessarily mean that the levels of the encoded protein would be also overexpressed. Further, the searches for the levels of mRNAs and the protein encoded by said mRNAs are not coextensive, and it would be a burden for the Examiner to examine all the claims together.

The requirement is still deemed proper and is therefore made FINAL.

Applicant amends claims 29, 30, 32, 34 and adds new claims 44-61. The amended claim 29 is rejoined with claims 30, 32, and 34, wherein claims 29, 30, 32, 34 and new claims 44-45, 50, 51, 56-57 are examined only to the extent of a method for identifying bladder cancer comprising detection the levels of mRNAs of 20P2H8 gene, and not a method for identifying bladder cancer comprising detection the levels of a protein encoded by 20P2H8 gene .

Since applicant has elected Group X, a method for identifying bladder cancer comprising detection the levels of mRNAs of 20P2H8 gene, for action on the merits for

the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the embodiments of new claims 44-61, directed to a method for identifying bladder cancer comprising detection the levels of a protein encoded by 20P2H8 gene have been withdrawn from consideration as being directed to a non-elected invention and a method for identifying bladder cancer comprising detection the levels of mRNAs of 20P2H8 gene will be examined. See 37 C.F.R. 1.142(b) and M.P.E.P. 821.03. Newly submitted claims 44-61 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The two methods differ in method steps and reagents used, since the structure of mRNAs is different from that of the encoded protein

Accordingly, claims 29, 30, 32, 34 and new claims 44-45, 50, 51, 56-57 are examined in the instant application, wherein claims 29, 30, 32, 34 and new claims 44-45, 50, 51, 56-57 are examined only to the extent of a method for identifying bladder cancer comprising detection the levels of mRNAs of 20P2H8 gene, and not a method for identifying bladder cancer comprising detection the levels of a protein encoded by 20P2H8 gene.

After review and reconsideration, claims 29, 30, 32, 34 and new claims 44-45, 50, 51, 56-57 require new restriction.

Election/Restrictions

Restriction to one of the following species is required under 35 U.S.C. 121:

Any one of the tissue samples recited in claim 34.

The species are distinct, because they have different properties and characterisitics.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be

accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN NGAH, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

September 25, 2002